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Group Art Unit: 1614

Attorney  
Docket: 32361

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Sir:

Enclosed is a PTO Form 1449 which lists citations which may be material to the patentability and examination of the above identified application. Also enclosed are copies of the references cited. These are submitted in compliance with the duty of disclosure defined in 37 CFR 1.56. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement under 37 CFR 1.56 is not to be construed as a representation that a search has been made, that additional matter which is material to the examination of this application does not exist, or that any or more of these citations constitutes prior art.

Merton D. Kozmicki

Dated: June 20, 2007

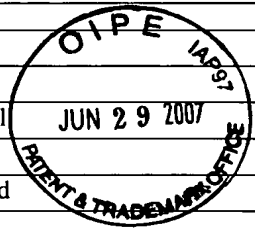
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

***Complete if Known***

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/589,623       |
| Filing Date            | August 16, 2006  |
| First Named Inventor   | Lola WEISS et al |
| Art Unit               | 1614             |
| Examiner Name          | Not Yet Assigned |
| Attorney Docket Number | 32361            |



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|------------------------|-------|

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages<br>or Relevant Figures Appear |
|--------------------|-----------------------|------------------------------------------|--------------------------------|----------------------------------------------------|------------------------------------------------------------------------------|
|                    |                       | Number-Kind Code <sup>2</sup> (if known) |                                |                                                    |                                                                              |
|                    | 1                     | US-4,371,720                             | 01-1-1983                      | Johnson et al.                                     |                                                                              |
|                    | 2                     | US-5,013,387                             | 07-7-1991                      | Goodwin et al.                                     |                                                                              |
|                    | 3                     | US-5,081,122                             | 01-14-1992                     | Ward                                               |                                                                              |
|                    | 4                     | US-5,292,736                             | 08-8-1994                      | Kumar et al.                                       |                                                                              |
|                    | 5                     | US-5,461,034                             | 10-24-1995                     | Rodan et al.                                       |                                                                              |
|                    | 6                     | US-5,618,955                             | 08-8-1997                      | Mechoulam et al.                                   |                                                                              |
|                    | 7                     | US-6,166,066                             | 12-26-2000                     | Makriyannis et al.                                 |                                                                              |
|                    | 8                     | US-6,403,123                             | 06-11-2002                     | Scott et al.                                       |                                                                              |
|                    | 9                     | US-6,410,588                             | 06-25-2002                     | Feldmann et al.                                    |                                                                              |
|                    | 10                    | US-6,531,636                             | 03-11-2003                     | Mechoulam et al.                                   |                                                                              |
|                    |                       |                                          |                                |                                                    |                                                                              |
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| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Documents                                                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|-------------------------------------------------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|----------------|
|                    |                       | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |                                                    |                                                                                 |                |
|                    | 11                    | PCT WO 00/19773                                                                     | 06-6-2000                      | Kochman et al.                                     |                                                                                 |                |
|                    | 12                    | PCT WO 98/41519                                                                     | 09-24-1998                     | Bender et al.                                      |                                                                                 |                |
|                    | 13                    | PCT WO 97/29079                                                                     | 08-14-1997                     | Inaba et al.                                       |                                                                                 |                |
|                    | 14                    | PCT WO 94/12466                                                                     | 09-9-1994                      | Mechoulam et al.                                   |                                                                                 |                |
|                    | 15                    | PCT WO 99/02499                                                                     | 01-21-1999                     | Inaba et al.                                       |                                                                                 |                |
|                    | 16                    | EP 0444451                                                                          | 04-4-1991                      | D'Ambra et al.                                     |                                                                                 |                |
|                    | 17                    | EP 0570920                                                                          | 11-24-1993                     | Mechoulam et al.                                   |                                                                                 |                |
|                    | 18                    | FR 2735774                                                                          | 09-12-1997                     | Rinaldi et al.                                     |                                                                                 |                |
|                    |                       |                                                                                     |                                |                                                    |                                                                                 |                |
| Examiner Signature |                       |                                                                                     |                                | Date Considered                                    |                                                                                 |                |

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |                       |                                                                                                                                                                                                                                                               |   | Application Number     | 10/589,623       |
|                                                                                                          |                       |                                                                                                                                                                                                                                                               |   | Filing Date            | August 16, 2006  |
|                                                                                                          |                       |                                                                                                                                                                                                                                                               |   | First Named Inventor   | Lola WEISS et al |
|                                                                                                          |                       |                                                                                                                                                                                                                                                               |   | Group Art Unit         | 1614             |
|                                                                                                          |                       |                                                                                                                                                                                                                                                               |   | Examiner Name          | Not Yet Assigned |
| Sheet                                                                                                    | 2                     | Of                                                                                                                                                                                                                                                            | 3 | Attorney Docket Number | 32361            |
| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS                                                        |                       |                                                                                                                                                                                                                                                               |   |                        |                  |
| Examiner Initials                                                                                        | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. |   |                        | T <sup>2</sup>   |
|                                                                                                          | 19                    | Adams et al. "Isolation of Cannabinol, Cannabidiol and Quebrachitol From Red Oil of Minnesota Wild Hemp", Journal of the American Chemical Society, 62: 2194-2196, 1940.                                                                                      |   |                        |                  |
|                                                                                                          | 20                    | Burstein et al. "Synthetic Nonpsychotropic Cannabinoids With Potent Antiinflammatory, Analgesic, and Leukocyte Antiadhesion Activities", Journal of Medicinal Chemistry, 35: 3135-3141, 1992.                                                                 |   |                        |                  |
|                                                                                                          | 21                    | Coffey et al. "Tetrahydrocannabinol Inhibition of Macrophage Nitric Oxide Production", Biochemical Pharmacology, 52: 743-751, 1996.                                                                                                                           |   |                        |                  |
|                                                                                                          | 22                    | Devane et al. "Isolation and Structure of A Brain Constituent That Binds to the Cannabinoid Receptor", Science, 258: 1946-1949, 1992.                                                                                                                         |   |                        |                  |
|                                                                                                          | 23                    | Edery et al. "Structural Requirements for Cannabinoid Activity", Annals of the NY Academy of Sciences, 191: 40-53, 1971.                                                                                                                                      |   |                        |                  |
|                                                                                                          | 24                    | Felder et al. "Anandamide, An Endogenous Cannabimimetic Eicosanoid, Binds to the Cloned Human Cannabinoid Receptor and Stimulates Receptor-Mediated Signal Transduction", Proc. Natl. Acad. Sci. USA, 90: 7656-7660, 1993.                                    |   |                        |                  |
|                                                                                                          | 25                    | Gaoni et al. "The Isolation and Structure of Δ <sup>1</sup> -Tetrahydrocannabinol and Other Neutral Cannabinoids From Hashish", Journal of the American Chemical Society, 93: 217-224, 1971.                                                                  |   |                        |                  |
|                                                                                                          | 26                    | Hanuš et al. "Two New Unsaturated Fatty Acid Ethanolamides in Brain That Bind to the Cannabinoid Receptor", Journal of Medicinal Chemistry, 36: 3032-3034, 1993.                                                                                              |   |                        |                  |
|                                                                                                          | 27                    | Hanuš et al. "2-Arachidonyl Glyceryl Ether, An Endogenous Agonsit of the Cannabinoid CB1 Receptor", Proc. Natl. Acad. Sci. USA, 98(7): 3662-3665, 2001.                                                                                                       |   |                        |                  |
|                                                                                                          | 28                    | Houry et al. "Benzoxocin and Benxoxonin Derivatives. Novel Groups of Terpenophenols With Central Nervous System Activity. A Correction", Journal of Medicinal Chemistry, 18(9): 951-952, 1975.                                                                |   |                        |                  |
|                                                                                                          | 29                    | Zuardi et al. "Antipsychotic Effect of Cannabidiol", Journal of Clinical Psychiatry, 56(10): 485-486, 1995.                                                                                                                                                   |   |                        |                  |
|                                                                                                          | 30                    | Formukong et al. "Analgesic and Antiinflammatory Activity of Constituents of Cannabis Sativa L.", Inflammation, 12(4): 361-371, 1988.                                                                                                                         |   |                        |                  |
|                                                                                                          | 31                    | Venstrom et al. "Survival After Pancreas Transplantation in Patients With Diabetes and Preserved Kidney Function", JAMA, 290(21): 2817-2823, 2003. Correction: 291(13): 1566, 2004.                                                                           |   |                        |                  |
|                                                                                                          | 32                    | Kendall et al. "Pancreas and Islet Transplantation", The Endocrinologist, 5: 28-35, 1995.                                                                                                                                                                     |   |                        |                  |
|                                                                                                          | 33                    | Mechoulam "Marijuana: Chemistry, Pharmacology, Metabolism and Clinical Effects", Academic Press, 65: Book Info & Table of Contents, 1973.                                                                                                                     |   |                        |                  |
|                                                                                                          | 34                    | Houry et al. "Benzoxocin and Benxoxonin Derivatives. Novel Groups of Terpenophenols With Central Nervous System Activity", Journal of Medicinal Chemistry, 17(3): 287-293, 1974.                                                                              |   |                        |                  |

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| Signature |  | Considered |  |
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

|                                                                                                   |                       |                                                                                                                                                                                                                                                               |                      |                        |                |
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|                                                                                                   |                       |                                                                                                                                                                                                                                                               | Filing Date          | August 16, 2006        |                |
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|                                                                                                   |                       |                                                                                                                                                                                                                                                               | Group Art Unit       | 1614                   |                |
|                                                                                                   |                       |                                                                                                                                                                                                                                                               | Examiner Name        | Not Yet Assigned       |                |
| Sheet                                                                                             | 3                     | Of                                                                                                                                                                                                                                                            | 3                    | Attorney Docket Number | 32361          |
| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS                                                 |                       |                                                                                                                                                                                                                                                               |                      |                        |                |
| Examiner Initials                                                                                 | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. |                      |                        | T <sup>2</sup> |
|                                                                                                   | 35                    | Mechoulam et al. "Hashish - I. The Structure of Cannabidiol", Tetrahedron, 19: 2073-2078, 1963.                                                                                                                                                               |                      |                        |                |
|                                                                                                   | 36                    | Mechoulam et al. "Identification of An Endogenous 2-Monoglyceride, Present in Canine Gut, That Binds to Cannabinoid Receptors", Biochemical Pharmacology, 50(1): 83-90, 1995.                                                                                 |                      |                        |                |
|                                                                                                   | 37                    | Mechoulam et al. "Recent Advances in the Chemistry and Biochemistry of Cannabis", Chemical Reviews, 76(1): 75-112, 1976.                                                                                                                                      |                      |                        |                |
|                                                                                                   | 38                    | Mechoulam et al. "Synthesis and Biological Activity of Five Tetrahydrocannabinol Metabolites", Journal of the American Chemical Society, 94(22): 7930-7931, 1972.                                                                                             |                      |                        |                |
|                                                                                                   | 39                    | Mechoulam et al. "Stereochemical Requirements for Cannabinoid Activity", Journal of Medicinal Chemistry, 23(10): 1068-1072, 1980;                                                                                                                             |                      |                        |                |
|                                                                                                   | 40                    | Mechoulam et al. "Chemical Basis of Hashish Activity", Science, 169(3945): 611-612, 1970.                                                                                                                                                                     |                      |                        |                |
|                                                                                                   | 41                    | Mechoulam et al. "Synthesis of the Individual, Pharmacologically Distinct, Enantiomers of A Tetrahydrocannabinol Derivative", Tetrahedron: Asymmetry, 1(5): 315-318, 1990.                                                                                    |                      |                        |                |
|                                                                                                   | 42                    | Murphy et al. "Cannabinoid Geometry and Biological Activity", Marijuana/Cannabinoids: Neurobiology and Neurophysiology, P.1-33, 1992.                                                                                                                         |                      |                        |                |
|                                                                                                   | 43                    | Leite et al. "Anticonvulsant Effects of the ( - ) and ( + ) Isomers of Cannabidiol and Their Dimethylheptyl Homologs", Pharmacology, 24: 141-146, 1982.                                                                                                       |                      |                        |                |
|                                                                                                   | 44                    | Zuardi et al. "Effects of Cannabidiol in Animal Models Predictive of Antipsychotic Activity", Psychopharmacology, 104(2): 260-264, 1991.                                                                                                                      |                      |                        |                |
|                                                                                                   | 45                    | Rhee et al. "Cannabinol Derivatives: Binding to Cannabinoid Receptors and Inhibition of Adenylylcyclase", Journal of Medicinal Chemistry, 40: 3228-3233, 1997.                                                                                                |                      |                        |                |
|                                                                                                   | 46                    | Robertson "Seminars in Medicine of the Beth Israel Hospital, Boston: Pancreatic and Islet Transplantation for Diabetes - Cures of Curiosities?", The New England Journal of Medicine, 327(26): 1861-1868,                                                     |                      |                        |                |
|                                                                                                   | 47                    | Petrzilka et al. "Synthese und Chiralität des ( - )-Cannabidiols", Helvetica Chimica Acta, 50, Fasciculus 2(73-74/Chap.74): 719-723, 1967.                                                                                                                    |                      |                        |                |
|                                                                                                   | 48                    | Sheskin et al. "Structural Requirements for Binding of Anandamide-Type Compounds to the Brain Cannabinoid Receptor", Journal of Medicinal Chemistry, 40: 659-667, 1997.                                                                                       |                      |                        |                |
|                                                                                                   | 49                    | Srebnik et al. "Base-Catalysed Double-Bond Isomerizations of Cannabinoids: Structural and Stereochemical Aspects", Journal of the Chemical Society, Perkin Transactions I, P.2881-2886, 1984.                                                                 |                      |                        |                |

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